

IN THE SPECIFICATION

V. E. Please amend the specification as follows, as required by the Examiner:

On page 3, line 27, please delete "As used in the claims, "a" can mean one or more."

IN THE CLAIMS

REMARKS

Claims 32-44 were originally pending in the present application. Of these, claims 32 - 44 were rejected. For the reasons discussed below, these claims are believed allowable.

CLAIM REJECTIONS

35 USC § 102

The Examiner has rejected claims 32-34, 39-41, 43, and 44 on the alternative grounds that the claims are either anticipated by or are obvious over U.S. Patent No. 5,411,474, previously granted to Ott, et al. ("474"). It is the Examiner's position that '474 teaches a method of providing heated and humidified gas for a period of time into a patient by directing the gas from a gas source to a chamber, humidifying the gas within the chamber with a liquid, sensing the humidity of the gas as it exits the chamber and monitoring the humidity of the gas exiting the chamber. The Examiner further believes that '474 teaches replenishing the liquid used for humidification, determining relative humidity of the gas, heating and filtering the gas (heating and humidification being performed simultaneously), sensing the temperature of the gas, and controlling the electrical power to the apparatus.

Applicant respectfully submits that the instant application is not anticipated by or obvious over '474 for the reasons that follow. Contrary to the Examiner's position, '474 neither directly nor indirectly teaches a method for sensing or monitoring of humidity levels of the gas. Primarily, '474 specifies that the humidity is not independently controlled (Table 1, col. 11, lines 32-33). Instead, the relative humidity is calculated pursuant to the selected temperature of the gas, selected gas flow rate, and porous bed characteristics (Table 1, col. 11, lines 14-36). Further, there is no feedback loop illustrated on Figure 3 demonstrating any communication or flow of information between a humidity sensor and the microprocessor of the apparatus. As such, there is

no mention of any humidity sensing means in either the specification or the claims of '474. In short, '474 does not directly teach a method for sensing or monitoring the humidity level of the gas.

Moreover, the Examiner's argument that humidity sensing is indirectly taught by '474 lacks any support. Applicant agrees that '474 does teach temperature regulation of a gas via "feedback temperature regulation of the heater/humidification chamber," which operates by sensing the temperature of gas exiting the heater/humidification chamber and sending a signal from the temperature sensing device to a temperature control circuit, which controls an electric resistance heater element that is embedded in the apparatus' humidification bed (column 6, lines 64-68 and column 7, lines 1-5 and column 8, lines 37-40). However, '474 does not teach sensing devices for pressure or volumetric flow of the gas because control of the pressure and volumetric flow of the gas is not maintained by the apparatus taught by '474. It is clearly specified in the patent that the gas to be treated by the inventive apparatus is "...received from an insufflator which receives gas from a gas source.... wherein the gas is pressure- and volumetric flow rate-controlled by the insufflator..." (column 3, lines 52-58). Therefore, control of the pressure and volumetric flow rate is not performed by the apparatus taught by '474 and actually occurs before the gas is even delivered to the apparatus. The apparatus does not include any means for sensing either the pressure or volumetric flow rate of the gas.

Finally, Applicant respectfully disagrees with the Examiner's unsupported conclusion that "...volumetric flow to and from the chamber in combination with the pressure and temperature will inherently control the humidity as controlled in Ott et al. by keeping the temperature within 2 degrees Celsius." A gas at any given temperature may have any relative humidity between 0% and 100%. Applicant is unaware of any direct thermodynamic relationship between temperature and humidity which would allow control of the humidity level solely by controlling the temperature of the gas.

A close reading of '474 clarifies the fact that the patent does not teach any sensing devices for pressure or volumetric flow of the gas. This point is acknowledged by the following

statement found in paragraph 5 of the Official Action: "Ott et al. teaches all of the limitations of the claims except for a humidity sensing" (emphasis added). For this reason, it cannot be argued that it would have been obvious at the time to one skilled in the art to combine the pressure and volumetric flow sensing devices with temperature sensing because there are no such devices taught by '474 to combine. For the foregoing reasons, Applicant maintains that '474 does not directly or indirectly teach humidity sensing and respectfully submits that the apparatus proposed by the instant application is not anticipated by or obvious over the apparatus taught by Patent No. 5,411,474 to Ott, et al.

35 USC § 103

The Examiner has also rejected claims 32-34, 38 and 39-44 on the additional basis that the claims are unpatentable over Ott, et al. ('474) in view of Nishino, et al. (U.S. Patent No. 4,276,128) on obviousness grounds. The Applicant respectfully submits that combination of the humidity sensing device taught by Nishino, et al. with the apparatus taught by '474 was not obvious to one skilled in the art at the time of invention. Nishino et al. teaches a solid state device that creates a signal from which the humidity level of the surrounding atmosphere may be measured. As previously discussed, '474 does not teach any sensing devices for pressure and volumetric flow which could have been combined with the temperature sensing device. Further, there is no support for the Examiner's proposition that control of the temperature will inherently control the humidity. Again, Applicant maintains that '474 does not directly or indirectly teach humidity sensing.

Applicant also respectfully points out that because '474 does not teach humidity sensing, it would not have been obvious to one skilled in the art at the time of invention to combine '474 with Nishino et al. to provide for humidity sensing. Humidity sensing was one feature that was later added by Ott et al. to improve upon the apparatus taught by '474 (see U.S. Patent No 6,068,609 to Ott et al.). In fact, '474 was incorporated in its entirety by reference into Patent No. 6,068,609 (column 1, lines 58-60).

The application at issue teaches sensing the humidity level of the gas and generating an alarm when the humidity of the gas in the chamber drops below a critical relative humidity threshold (see claim 38 of the instant application). It is further specified in the application that this alarm may be audible and/or visual, such that it will warn the medical attendant or user that the heater/hydrator requires recharging (p. 23, lines 16-18). Regardless of the actual form, the intended purpose of the alarm is to provide a means for annunciating the need for recharge of the liquid supply in the heater/hydrator.

Further, the instant application does not claim any method for humidity sensing, but does specify inclusion of a humidity-sensitive capacitor as taught by Nishino et al. (p. 11, lines 12-14). Any commercially available humidity-sensitive capacitor may be used to provide the humidity sensing capability to the inventive apparatus. The application at issue therefore not only contemplates use of a humidity-sensitive capacitor, but also includes an additional alarm feature. Combination of '474 with Nishino et al. may have given rise to an apparatus having a humidity sensing element, but would not have provided for any alarm to annunciate the need for recharge. Therefore, even if '474 and Nishino et al. had been combined, the combination would not yield an apparatus including all the aspects taught by the instant application.

Finally, the Examiner has also rejected claims 35-36 and 38 under 35 U.S.C. § 103(a) as being unpatentable over Ott, et al. in view of Absten, et al. (U.S. Patent No. 5,246,419). Applicant respectfully disagrees with the Examiner's assessment of the teachings of Absten, et al. Particularly, Absten, et al. teaches an apparatus for supplying insufflation gas at high flow rates during laparoscopic surgery (column 2, line 43-45). Absten, et al. also teaches that one element of the typical embodiment of said apparatus would include a pressure sensor, *i.e.*, at least one pressure gauge, connected to a microprocessor to automatically reduce the gas flow when a predetermined limit is exceeded (column 5, lines 36-39). Thus, Absten, et al. describes an apparatus including a microcontroller used to measure and maintain gas pressure.

Absten, et al. uses the terms "alarm" and "alarm points" to refer to the means for controlling the humidity level which may be included in the apparatus (col. 5, lines 30-32 and 65-

67 respectively). As used by Absten, et al. these are the set points at which the microprocessor would trigger a decrease of the gas flow by means of valves (col. 5, lines 22-32 and 67). The terms do not, however, refer to an alarm such as is taught by the application at issue, i.e., a means by which the medical attendant or user may be warned that the heater/hydrator requires recharging (p. 23, lines 16-18). At most, Absten, et al. suggests an embodiment of the apparatus that would only display a measured pressure in the event that a problem was detected. Absten, et al. does not, however, claim such apparatus or teach any means for alerting a user of a problem independent of a display of the pressure.

In consideration of the fact that Absten, et al. does not teach an alarm mechanism comparable to that taught by the application at issue, combination of '474 and Absten, et al. would not yield an apparatus including all the aspects taught by the instant application. For this reason, Applicant respectfully submits that the Examiner's rejection of claims 35-36 and 38 under 35 U.S.C. § 103(a) have been overcome.

Double Patenting

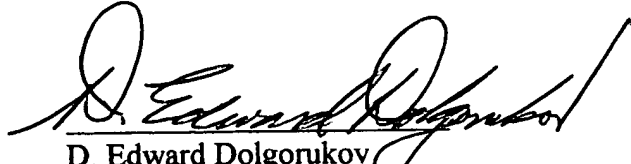
The Examiner has rejected claims 32, 39, 41, 43 and 44 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-15 of U.S. Patent No. 5,411,474. As previously discussed, the instant application is patentably distinct from claims 11-15 of '474. First, the instant application teaches an additional aspect of sensing the humidity of the gas as it exits the chamber and monitoring the humidity of the gas exiting the chamber, which are not taught by '474. Second, the instant application teaches a step of generating an audible and/or visible alarm when it is determined the volume of liquid in the chamber requires replenishing. Third, the instant application teaches a step of recharging the chamber with liquid in response to the alarm.

None of the above-mentioned aspects are taught by claims 11-15 of '474. Specifically, these claims only teach a method of providing heated, humidified gas into a patient by directing a gas from a gas source via an insufflator into a chamber, simultaneously heating, humidifying and filtering the gas in the chamber, sensing the temperature of the gas exiting the chamber, actuating

the heating means if the temperature of the gas is without the predetermined range, and filtering the gas a second time after it is heated and humidified.

For these reasons, the claims now pending in the instant application are patentably distinct from claims 11-15 of U.S. Patent No. 5,411,474.

Respectfully submitted,



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